10/535110
PCT/AU03/01526

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I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003903586 for a patent by DAVID PETER WHARTON as filed on 11 July 2003.

WITNESS my hand this
Twenty-sixth day of November 2003

JANENE PEISKER
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SUPPORT AND SALES

Regulation 3.

David Peter Wharton

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

for the invention entitled:

"Drug Delivery Device and Method"

The invention is described in the following statement:

DRUG DELIVERY DEVICE AND METHOD

FIELD OF THE INVENTION

The present invention relates to a device and method for delivery of a drug or drugs to a target organism via the respiratory system. In particular, the invention relates to delivery of drugs to a target organism by entraining the drug in an air stream which may be pressurised. More specifically, in one aspect, the present invention relates to the delivery of a drug or drugs in a pressurised air stream when the recipient is in ambient conditions of increased or decreased atmospheric pressure and reliant on a pressurised respiratory gas supply such as scuba diving under water. In a further aspect, the invention relates to a device and method for medicating an air supply at ambient air pressure such as when a person is using a snorkel at or near the surface of a body of water.

BACKGROUND OF THE INVENTION

The development of self contained underwater breathing apparatus ("scuba") has revolutionised underwater diving for both recreational and professional divers. The simplicity and reliability of modern scuba gear has extended the range and scope of diving activities to a much broader spectrum of society than originally envisaged when the prototype was successfully tested in 1943.

The range of available diving activities extends from simple recreational pursuits through to specialised activities such as cave, ice and wreck diving. In warmer waters and particularly in tropical and subtropical areas near coral reefs, there is a great demand for diving tuition, diving expeditions and involvement in general basic diving activities.

In order to be a suitable candidate for undertaking scuba diving, it is necessary to have at least reasonable health with no major relevant disease conditions.

Perhaps the commonest obstacle to scuba diving is asthma, which is both a pervasive disease in society and an exclusionary condition when considering diving. The incidence of asthma has been estimated variously at 10% in Australia and New Zealand, 4-7% in the USA and 6-8% in the United Kingdom. Even mild signs of the disease may be sufficient to disqualify participation in scuba diving, as the obstructive effect of this condition is very marked. It has been noted that asthma increases the risk of lung barotrauma and represents a contraindication to diving (Heritier and Russi, *Journal Suisse de Medicine* **123(5)**:161-165, 1993). This blanket exclusion has been questioned. The question of bronchodilator inhalation prior to diving has been given some consideration (Coetmeur *et al.*, *Revue des Maladies Respiratoires* **18**:381-386, 2001) but without any controlled studies. This approach runs the risk of inappropriate medication or, more significantly medication at a time removed from the trigger event or onset of bronchoconstriction.

Experienced diving instructors will relate many stories of otherwise seemingly perfectly healthy people being excluded from diving classes and the rewards of a diving experience, even when that person is asymptomatic. One perceived risk for such a person participating in scuba diving is that a sudden onset of a severe attack at any depth, or even on the surface, could have catastrophic and even fatal consequences. As pressure increases by one atmosphere for every 10 metres of depth, even at a depth of 5 metres, a diver must accommodate a 50% increase in ambient pressure. Respiratory embarrassment, even at this depth, may have significant adverse consequences. One of the unpredictable aspects of asthma is that severity of episodes of dyspnoea is highly variable and also unpredictable.

The problem is not confined to scuba diving and may also arise when a person is snorkelling. The onset of difficult breathing may arise on the surface or while diving below the water level.

Aerosol medications are extremely well known for effective therapeutic intervention in an asthma attack when a victim is in normal atmospheric

conditions. However, to date, it has not been possible to provide access to such therapeutic agents under water in scuba diving or snorkelling. Likewise, powder and liquid therapeutic agents may also be administered via the respiratory system.

It should be noted that while the following disclosure is directed primarily to scuba diving arrangements and snorkelling arrangements, it is possible to transfer the same device and method to a wider range of situations for use with pressurised respiratory air supplies. Also, the term drug is used in its widest sense to include agents that are both therapeutic and recreational and agents which may have a mechanical effect on the respiratory tract such as maintaining moisture content or providing a surfactant activity or similar. Further reference to asthma is exemplary only and other respiratory diseases or diseases treatable via the respiratory system may also be suitable for application of the present invention. This is particularly so in relation to diseases or physiological effects due to increases and decreases of ambient pressures such as nitrogen narcosis, C.N.S. effects and reaction to increased partial pressure of compounds in the inhaled gas where treatable via respiratory system.

It would be advantageous to provide a means of delivering a drug to a patient in a pressurised or unpressurised air stream under water or on or near the surface of a body of water.

SUMMARY OF THE INVENTION

Throughout this specification, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element or integer or group of elements or integers but not the exclusion of any other element or integer or group of elements or integers. Reference to "air" includes a reference to gas or gas combinations suitable for breathing. Relevant examples include Nitrox and Heliose products.

In one aspect, the invention resides in a dosage device for medicated respiration

in a breathing apparatus, the dosage device comprising:

a chamber adapted to store and discharge a therapeutic agent;

a delivery pathway between the chamber and an intake air pathway of the breathing apparatus; and

releasing means for selectively discharging the therapeutic agent into the intake air pathway.

The therapeutic agent may be housed in a container, the container dimensioned to locate in the chamber.

The dosage device may further comprise balance means for substantially equalising the pressure between the chamber and ambient pressure.

The chamber may form part of a regulator arrangement for a pressurised breathing apparatus. Alternatively, the chamber may be in operative proximity to a portion of a regulator arrangement. The chamber may be arranged for cooperation with an airline of an under water breathing apparatus.

The container for storing and discharging a therapeutic agent may be a pressurised canister. The pressurised canister may have a release valve which is pressure activated. The container may deliver a preselected dosage of agent. The agent may be one or more of salbutamol (Ventolin®), adrenaline, beconase (Becotide®) or any other suitable agent. The container may form part of a nebuliser arrangement, wherein intake of respiratory gases causes an aerosol to be produced and entrained in the intake air. The nebuliser arrangement may include a venturi assembly. Alternatively or additionally, the container may comprise a polymeric capsule or a gelatine capsule or other suitable arrangement.

The therapeutic agent may be one or more of a solid, preferably a powder, a liquid or a gas.

The pathway between the chamber and an intake air pathway may arise simply

from the chamber being disposed along the intake air pathway. Alternatively, the chamber may communicate with the intake air pathway through at least one bore. The pathway may be a detour air pathway.

The bore may include valve means operable to open and close the bore. The valve means may be a slide lock. The slide lock may include a locking nut to prevent unintentional activation. The slide lock may include a positioning device such as a pin for indicating when the slide lock is in suitable position to open the bore.

The device may include two or more pathways between the chamber and an intake air pathway.

The breathing apparatus may comprise scuba gear or part thereof. The breathing apparatus may comprise a snorkel.

The balance means may comprise a compressed air supply source, an intake valve means, an outlet valve means and pressure deformable means for responding to variations between pressure inside the chamber and outside water pressure, wherein the pressure deformable means will release the inlet valve when water pressure significantly exceeds chamber pressure and the outlet valve will release air when the chamber pressure significantly exceeds water pressure.

Preferably, the compressed air source is an off-shoot of a primary air line of the breathing apparatus.

In a further aspect, the invention resides in a dosage arrangement for medicated respiration in a breathing apparatus comprising:

an air supply line;

a second stage regulator chamber connected to the air supply line;

a medication chamber operatively connected to the second stage chamber by at least one air pathway;

a medication canister mounted in the medication chamber and arranged to discharge its contents into the pathway;

a secondary air supply line originating from the air supply line and providing air to the medication chamber;

an intake valve for controlling air delivery to the medication chamber from the secondary air line;

an exhaust valve for discharging air from the medication chamber;

a deformable diaphragm located between ambient water and the medication chamber;

where:

the deformable diaphragm activates a release lever to provide air to the medication chamber when ambient water pressure exceeds the pressure of the medication chamber; and

the exhaust valve releases air from the medication chamber when the air pressure of the chamber exceeds ambient water pressure.

The device may include a pathway control valve for opening and closing the at least one air pathway. The control valve may be a slide lock. The slide lock may have an indicator seal for indicating when it has been used. The slide lock may be held in place by a lock nut. Alternatively or additionally, the device may have a trap door arrangement, a lever arm arrangement or a removable plug as the control valve.

Preferably, the device includes two communicating pathways from the medication chamber to the second stage chamber. The two pathways may be aligned with discharge apertures in the medication canister. The discharge apertures may be opened by pressure. Pressure may be applied by an operator through a deformable pad located in a side of the medication chamber. The medication canister may discharge into air flow pathway.

In a further aspect, the invention resides in a pressurised canister for storing a therapeutic agent. The pressurised canister may be formed with a lower amount

of agent and at higher pressure than known devices. Further, the canister may have at least two discharge apertures. The apertures may be adapted for simultaneous discharge or may include a mechanism for providing selected discharge through one of the apertures. The canister is preferably adapted for use in the dosage device described above.

In a further aspect, the invention resides in a snorkel with a discharge means for discharging a therapeutic agent mounted for operation to medicate inhaled air; and control means for activating discharge of the therapeutic agent. The discharge means may be a canister. The canister may be pressurised. The canister may have a therapeutic agent release mechanism activated by externally applied pressure.

The discharge means may be a nebulising arrangement. This discharge means may include a venturi airflow arrangement.

The discharge means may be located externally of an air pathway in the snorkel. Alternatively, the discharge means may be positioned within the air pathway.

The therapeutic agent may be one or more of salbutamol, beconase, adrenaline aminophyeline or other suitable compound or mixture.

The control means may be a rotatable barrel. The barrel may be formed as a semi-cylindrical or longitudinally sectioned cylindrical device. The barrel may be positionable to either occlude an air pathway between a nozzle of the medical canister and the mouthpiece or open the air pathway. The control barrel may be operated by a finger operated lever or twist grip. The control barrel may be rotatably mounted at each end.

The canister may be mounted in a medical chamber connected to the main snorkel. The medical chamber may be sealed to prevent or resist the ingress of water. The canister is preferably operated by application of externally applied

pressure resulting in opening of a control valve in the canister. The canister may contain salbutamol.

The air pathway may be opened by an alignment of a void in the control barrel and a vent in a wall of the main snorkel. The air pathway may be opened by alignment of a piston and vent.

In an alternative embodiment, the control barrel may be mounted in the medical chamber. The medical chamber may be closed by a screw threaded end cap. The end cap is preferably sealed. The screw threaded end cap may include a deformable membrane for applying pressure to an end of the medical canister. The medical chamber may include a water trap.

The discharge means may comprise a nebuliser arrangement. The nebuliser arrangement may include a venturi assembly.

Alternatively, the discharge means may comprise a rotatable blade or blades for dispensing a powder or liquid into an intake air stream.

The control means may comprise a flow control valve for directing air through a detour air pathway additional to the main air pathway of the snorkel.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a front view of a dosage device of the present invention.

Figure 2 is a bottom view of the arrangement of Figure 1.

Figure 3 is a side schematic view of an alternative arrangement for dosing a pressurised airstream.

Figure 4 is a back view of a snorkel and barrel located in the main snorkel.

Figure 5 is an end view of the arrangement of Figure 4.

Figure 6 is a front view of an arrangement in which a control barrel is located in a medical chamber attached to a snorkel.

Figure 7 is an end view of the arrangement of Figure 6.

Figure 8 is a schematic sectional view of an alternative embodiment of an arrangement of the present invention.

Figure 9 shows a range of external views of a further embodiment of the present invention.

Figure 10 shows sectional views of the embodiment of Figure 9.

Figure 11 shows enlarged views similar to those of Figure 10.

Figure 12 shows a variation of the arrangement of Figure 11.

Figure 13 shows a further embodiment of a pressurised canister regulator.

Figure 14 shows an arrangement for delivery of a dry agent through a snorkel.

Figure 15 shows an arrangement for delivery of a dry agent through a regulator.

Figure 16 shows an alternative arrangement for delivery of a dry agent through a snorkel.

Figure 17 shows an alternative arrangement for delivery of a dry agent through a regulator.

DETAILED DESCRIPTION OF THE DRAWINGS

Scuba diving developed from the technological advance of providing an oxygen mixture under high pressure in a tank with a pressure reducing mechanism for providing the mixture to a person's lungs sufficiently decreased to avoid injury. The principle development related to the production of a regulator for use with either compressed air (78% nitrogen, 21% oxygen) or an oxygen enriched nitrogen oxygen combination called NITROX, which includes a range of suitable mixtures. However, the most common range is 64-68% nitrogen and 32-36% oxygen. This gas mixture will be typically held in a metal cylinder which holds approximately 2,200 litres of mixture at approximately 180-230 ATM atmospheres of pressure (ATM).

The regulator is usually provided having a first stage and second stage function. The regulator is adapted to provide air on demand by a user and also reduce the pressure as required.

The first stage of a regulator may attach to the cylinder of air and is designed to reduce pressure from the tank at around 204 ATM to an intermediate pressure of around 9.5 ATM.

A length of flexible extendible hose is usually then provided to connect the first stage to the second stage of the regulator. The second stage is adapted to reduce the mixture at 9.5 ATM to ambient water pressure which is usually in the range of 1-5 ATM depending on depth. The second stage also includes the mechanism for providing air inlet which is activated by inhalation by the diver or, in some circumstances, has an override for providing air continuously such as in an emergency situation.

The structure of the first stage includes high pressure and intermediate pressure chambers which usually have either a valve diaphragm combination or a piston which are effected by water pressure.

High pressure air is delivered to the first chamber but is subject to controlled release into the second chamber from the action of the diaphragm or piston.

Commonly, the act of breathing will decrease pressure in the secondary chamber leading to an imbalance between the pressure of the air in the chamber and the pressure of surrounding water. A resilient diaphragm may be deformed to activate a push valve, thereby clearing a seat and allowing high pressure air from the first chamber into the second chamber. An alternative arrangement uses a somewhat similar function but is based on a hollow piston which moves into and out of register with a cooperating seat with an alternatively closed and clear connecting passageway.

The second stage of the regulator is located adjacent and includes the mouth piece. The second stage has a chamber with a rubber diaphragm in contact with ambient water pressure and an inner valve that is connected to a moveable lever. The second stage also includes an exhaust valve and often has a purge button.

On inhalation, the pressure within the second stage drops below the ambient water pressure. As a result, the diaphragm is distorted and comes in contact with the lever which is pivotally mounted and is rotated, thereby clearing an inlet line from the tank. This air is inhaled.

On expiration, the pressure in the second stage of the regulator is increased leading to closure of the air inlet, pressurisation of the diaphragm away from the lever and opening of the exhaust valve.

The above cyclical process is performed sequentially and constantly. The purge button may be used to clear water from the mouth piece and the second stage chamber by introduction of a large quantity of pressured air or gas mix.

Figure 1 shows a front view of a dosage device 10 of the present invention. A

primary air line 11 provides a pathway for air 12 or gas mixture originating from the pressurised tank on a diver's back. The primary air line 11 terminates in a demand valve 13 which operates in the standard way for delivering pressurised air into the second stage chamber 14 which is shown drawn only in part having partial side walls 15, 16.

A bifurcation results in secondary line 17 which provides compressed feed air to the dosage device 10 of the present invention. It is understood that reference to compressed air includes reference to any appropriate compressed gas or gas mixture including oxygen and nitrogen combinations such as NITROX and other gaseous combinations. The dosage device 10 comprises an outer housing 18 which may be formed from any suitable non-flexible material such as metal or polymer. A drug containing canister 19 is positioned in an internal chamber 20 of the dosage device 10.

It is envisaged that the canister 19 will contain a pressurised quantity of therapeutic agent or other form of physiologically or mechanically active substance with a discharge mechanism that is pressure activated. The canister 19 is mounted on two ledges 21 and compressed in place by a suitable packing material such as a tension foil 22. The canister 19 has two outlet apertures 23, 24 which are urged into close proximity and sealing engagement with the discharge bore. When not in use, the apertures abut a lock slide 25 which may be formed with a security seal 26, the purpose of which is to indicate when the device has been operated, thereby indicating to an overseeing diving instructor, health professional or other suitable party, such as a service or technical agent, that the canister may be depleted. In a preferred embodiment, it is envisaged that the canister will be a one use item which may include a number of activations of the device which is disposed of after any single dive in which the device is operated. The lock slide 25 has two through bores 27 which are usually out of alignment with the outlet apertures 23, 24. However, when the device is to be used a rotatable lock screw 28 may be released providing the ability to slide lock slide 25 to a position where the through bores 27 and outlet apertures 23, 24 are in corresponding alignment,

thereby providing a pathway from the outlet apertures through the through bores and into flow channels 29, 30 directed towards the air stream in the chamber 14 and for inhalation through the mouth piece (not shown). The slide is preferably sealed to prevent ingress of water. O-ring seals may be appropriately located to provide this function. Further, the canister apertures 23, 24 may be adapted to sealingly engage the slide rod when the through bores 27 are aligned. O-rings may again be suitable for the purpose.

The present device has an internal chamber 20 which is equalised with ambient water pressure through the demand valve 31 and demand valve lever 32. If the pressure in internal chamber 20 drops below ambient water pressure, the balance diaphragm 33 expands urging the demand valve lever 32 out of its resting position and thereby unseating a valve to allow inlet of air at high pressure into the chamber 20. Should the pressure in the chamber 20 exceed ambient water pressure, air may be discharged through exhaust valve 34. The exhaust valve release pressure of the chamber may be set slightly higher than ambient pressure (ie. increased activation pressure differential required) or the demand lever may be adapted to activate at an increased pressure differential so that the chamber is generally slightly below ambient pressure. The internal chamber 20 is protected by a chamber seal 35 which abuts a spacer 36 which is in itself in contact with a rubber cover 37. This view also shows an exhaust tube for discharge gas from primary and internal chambers 38.

In operation, therefore, a diver will breathe as usual in a scuba diving arrangement. Should the diver find themselves requiring medication of some sort, they will simply unlock the lock slide 25 by rotation of the lock screw 28 and slide the lock slide 25 outwards thereby breaking the seal 26. The lock slide may be fitted with a slide location pin 39 for fixing the lock slide in operating position. Once a pathway is provided between the canister apertures 23, 24 and the flow channels 29, 30, an operator pushes on the rubber cover 37 which leads to depression of the spacer 36, seal 35 and subsequent pressure on the canister 19 leading to activation of the normal discharge aerosol valve as is well known in

medihalers such as Ventolin® and Becotide®. The appropriate number of depressions may be applied to medicate the diver. On completion, the lock slide 25 may be urged back to its original position and the lock screw 28 may be located into locked position. While compression of the canister is described, it is clear an alternative arrangement may incorporate compression of a movable plate or other structure relative to the fixed canister.

Figure 2 shows a bottom view of the arrangement of Figure 1 with the exhaust line 38 readily apparent as is the primary exhaust valve 40 which is slightly spaced from medical chamber exhaust having a medical chamber exhaust cover 42. The side wall 43 of the primary regulator chamber is also visible and the primary air line 11 and chamber air line 17 terminating in demand valve 31 and lever 32. The balance diaphragm 33 is visible in close proximity to purge cover 44. The slide 25 and slide lock 28 are provided. Rubber cover 37 is apparent and may have a ridged thumb grip 45. A diaphragm seal is located and outlines medical canister 19 which is shown as visible but may in fact be located behind the outer material.

The present device is suitably adapted for one-handed operation by a diver. The hand may grip the chamber wall 43 with a thumb located over thumb operation pad 45 after having released the lock nut 28 and slid lock slide 25 into channel defining location. The canister 19 may be compressed by the thumb of the appropriate number of times as indicated by the manufacturer or in keeping with the advice of a medical professional.

An alternative arrangement is shown schematically in Figure 3 wherein the drug is delivered to the regulator. In this case, a canister 50 is positioned in a bracket 51 formed in the wall 52. A plunger 54 is slideably mounted in a secondary bracket 55 and is actioned by a pivotted lever 56, which is supported on pivot point 57 and rotatably engages the plunger at pivot pin 58.

In turn, the push rod 59 is slideably engaged in clips 60. An activation lever 61 is supported around rotation axis 62 and is resiliently biased to an extended position

by spring 63. O-ring seals 64 are used to maintain the integrity of the chamber and prevent any ingress of water. A twist lock 65 is also provided to prevent inadvertent activation of the device.

In use, the twist lock 65 is released and the activation lever 61 is depressed one or more times resulting in movement of push rod 59 and subsequent see-sawing action of the pivotted lever 56 causing the plunger 54 to depress and discharge contents of the canister 50 through the discharge aperture 66 and into flow tunnel 67, thereby entraining the medication in the air stream and providing it for respiration by a user.

Referring to Figure 4 there is shown a dosage device for medicated respiration of a breathing apparatus, wherein the medical canister is located in working position with a snorkel. This arrangement provides a mechanism for people to snorkel with the option to medicate their intake air.

The main snorkel 50 includes a flexible section of flex hose 51. Air is breathed through the main snorkel after location of the mouth piece 52 in the buccal cavity of a user.

Exhaled air is exhausted through exhaust valves 53 and the arrangement and operation is conventional other than for the presence of a chamber barrel 54. The chamber barrel 54 is pivoted at one end on pivot point 55 and at the other end through an axle 56 located through an aperture 57 and sealed by O-ring 58. The chamber barrel 54 is therefore rotatable within the bore of the snorkel 50. The axle 56 terminates in a twist lever 59 which may be finger operated. The aperture 57 is formed in an end cap 60 of the snorkel. The exhaust valves 53 are located under an exhaust valve cover 61. The chamber barrel 54 has a vent opening 62 shown in hidden detail which may be rotated into communication with the airflow through the main snorkel 50. This communication provides a delivery path for medication which is injected through aerosol discharge. Typically, the chamber barrel 54 will be positioned to occlude the vent opening 62. In operation, a user

will rotate the barrel until further progress is prevented by rotation stopper 63 which will indicate to a user that the necessary communication is provided by alignment of the vent opening 62.

Figure 5 is an end view of the arrangement of Figure 4. A chamber barrel 54 is apparent as the end cap 60 has been removed. As can be seen, an outer wall 64 of the chamber barrel 54 is located across the communicating vent 62 formed in a medical chamber 65 thereby obstructing communication between the medical chamber and the main airflow pathway of the main snorkel 50. The outer wall 64 forms a semi-cylindrical section with two internal walls 67 pivoted on a central rotation axis through the axle 56.

As shown in the present view, the internal wall 66 is located in abutting contact with the rotation stopper 63. In operation, a user grabs twist lever 59 and rotates the chamber barrel until the void 68 is located over the vent opening 62. A user is aware of this alignment when the second internal wall 67 contacts the rotation stopper 63.

At this stage, a user may depress the medical canister 69 to provide a discharge of aerosol medication through nozzle 70 into the medical chamber 65, thereby pressurising the medical chamber and discharging contents through the void 68 and into the air pathway of the main snorkel 50. An appropriate number of depressions of the medical canister may be provided to deliver a preferred or preselected amount of therapeutic agent or to effect as necessary. A seal 71 provides a water tight seal around the vent opening 62. Preferably, a water trap 72 is provided in the medical canister to trap and remove any small amounts of moisture that find their way into the chamber and thereby ensure that it does not interfere with or otherwise occlude operation of the dosage delivery system.

An alternative arrangement is shown in Figure 6 in which the control barrel is actually located in the medical chamber rather than in the main snorkel bore. In this description, like numbers indicate like parts. Again, the main snorkel 50

provides an air pathway and includes the flexible hose section 51. A user places the mouth piece 52 in his or her mouth and moves air through the bore of the main snorkel 50 in keeping with their respiratory activity.

The medical chamber 75 is provided with a rotatable control chamber barrel 76 rotatably mounted at a first seat 77 and with an axle 78 at the other end located in aperture 57. The axle 78 terminates in a twist grip 79 which provides a user with rotational control of the chamber barrel 76. The chamber barrel 76 includes a vent opening 80 (shown in hidden detail). A medical canister 81 is mounted in the medical chamber 75 with its discharge nozzle 82 aligned with an opening 83 into the chamber barrel 76. The medical canister 81 may be fixed in position by using a screw thread 84 on the medical canister 81 which is engageable with a support system. The medical chamber may be sealed by a screw cap 85 having an internal thread for engaging the screw thread 84 on the outside of the medical chamber 75. Seals 89 may be provided. A rubber end cap 86 may be provided with a thumb receiving section 87 for a user to pressurise an end 88 of the medical canister 81, thereby causing discharge of the contents. In an alternative arrangement, a movable member, such as a flange, may be positioned to pressurise the nozzle 82 while canister 81 is static.

Figure 7 shows an end view of the arrangement of Figure 6. A main snorkel end cap 59 closes the bore of the main snorkel 50 and exhaust valves 53 are provided with an exhaust valve cover 61 for discharge of exhaled gases and water.

This view is modified to highlight the operation of the chamber barrel 76 which is formed as a vertically sectioned cylinder defining a void 90. An outer wall 91 of the chamber barrel 76 is ordinarily located across the vent opening 80 to occlude the opening and thereby separate the medical chamber 75 and isolate it from usual airflow in the snorkel.

When required, a user applies rotational force to the twist grip 79, thereby leading to rotation of the chamber barrel 76 until the void 90 is located in alignment with

the vent opening 80. This may be positively established by contact of the barrel wall 92 with a rotation stopper 93. In this position, an air pathway is created between the nozzle 82 and the mouth piece 52 such that compression or pressure placed on the medical canister 81 provides a pressurised discharge of medicament into the airstream.

Again, a water trap 94 may be provided and a flow spacer 95 may be used to positively direct the flow towards the mouthpiece. An O-ring 96 seal prevents inflow of water.

The advantages of the present invention are readily apparent. The anxiety and real risk of a disease which is treatable via the respiratory tract is to a large degree addressed. A sufferer may, with adequate medical consultation, undertake pursuits which have previously been removed from their experience. The invention may be relatively cheaply constructed but also provides a high level of reliability and security. The types of drugs, medication or other compounds used is limited only by the availability of materials suitable for the present indications.

Likewise, the present invention may have an operation in applications other than scuba diving or snorkelling. In a situation where a conscious breathing individual is reliant on a pressurised air stream and requires any form of agent to be administered in that air stream, the dosage device described above may provide the opportunity for sensible self medication.

Figure 8 shows an arrangement in which a discharge canister is positioned above the mouthpiece. The canister 19 is located to discharge into internal chamber 20, which is sealed by flap 191. Seals 192 provide a closed compartment and separated from second stage chamber 14.

The flap 191 is held in place by spring 193. A lever 194 is provided for opening the flap 191, as shown in hidden detail. A user applies rotational force to the lever to open the flap and provide communication with second stage chamber 14. The

canister may then be activated to discharge through nozzle(s) 23, 24. A medical chamber exhaust feed 195 is also provided.

A series of views of one embodiment suitable for use with a snorkel is shown in Figure 9. The dosage device 110 has a connection point 111 for flexible hose section and mouthpiece 112.

Further views are apparent in Figures 10 and 11, where sectional diagrams display the disposition of operative parts. A medical canister 113 is positioned in chamber 114. A spring 115 is coiled around the canister 113 and supports piston housing 116. Depression of the button causes the piston 118 to move the nozzle 119 and discharge contents through passage 120, which moves to align with administer point 121. A lock ring 122 may be provided for releasing the device for operation. An end cap 123 provides access to chamber 114 to allow replacement of the canister 113. Purge valves 124, 125 may also be provided for clearing the chambers.

In Figure 12, the arrangement is similar to that of Figure 11 but includes a spring 130 positioned between the end cap 123 and medical canister 113.

Figure 13 is a sectional view of an arrangement 210 of a pressurised canister with a regulator. The canister 211 is positioned in a housing 212 adapted to telescopically shorten. A button 213 is provided to pressurise the canister 211 against the biasing action of spring 214 and discharge a metered dose of agent into the delivery area 215. A trap door arrangement 216 is provided to occlude the medication outlet 217. The trap door may be displaced by mechanical activation by a user or, alternatively, may be displaced by the pressure of released agent. Once released, the agent is inhaled by the person using the regulator. Other standard components of the arrangement include mouthpiece 218, a pressure balance tube 220, an airflow separation valve 221, an air hose connection assembly 222 and diaphragm and purge exhaust valves 223. The housing 212 is also provided with exhaust and purge valves 219.

While the description has been directed to aerosol producing, pressurised containers and also to gaseous and liquid agents, there are other important forms of medication. Many respiratory deliverable agents are now in a solid and particularly a powdered form. These are often inhaled from a delivery dose fed to the air stream, or in some cases, through impellers, activated by inspiration. The use of these and associated agents also are provided for by the present invention. Likewise, the range of medications suitable for the present application can be expected to grow with time and new drug development. The present invention will be suitable for many if not all of these agents.

Figure 14 shows a dry powder arrangement for a snorkel in inactive 310A and active 310B deployment.

The snorkel 311 includes a housing 312 having a rotating disk 313 which provides a measured portion of therapeutic agent 314. A twist top 315 allows delivery of the agent 314 to an inhalation area 323. An air inlet 316 is occluded by a valve 317. A medication outlet 318 is occluded by a valve 319. The valves 317, 319 are supported on a rotatable arm 320 pivoted at hinge point 321. Exhaust vents/purge valves 322 are also provided. In ordinary use access to the medication is prevented and air is inspired and exhaled in the direction of arrow 324 and through mouth piece 325.

Arrangement 310B shows the valves 317, 319 opened to provide an alternative air pathway through the medication canister or housing 312. Air now flows inwardly along direction of arrow 326 and picks up medicated powder 314. The rotatable arm 320 and valves may occlude the usual airway to maximise flow through the medical delivery apparatus. It is clear to a skilled person that other additions such as rotatable impeller may also be included in the device to potentiate agent delivery.

Figure 15 shows an arrangement for a regulator. The device 410A is in an

inactive state while the device 410B is activated. The regulator 411 has standard regulator diaphragm and purge/exhaust valves 412. Usual airflow is shown by arrow 413 from delivery line 414 to mouthpiece 415. A canister 416 is arranged containing a therapeutic agent 417 in powder form. A twist top 418 operates a rotatable disk 419 to disperse a predetermined dosage. On operation the powder is delivered to an inhalation area which communicates with a delivery tube 421. A medication outlet 422 is occluded by a valve 423 supported on rotatable arm 424 pivoted at hinge point 425. An air inlet 426 is occluded by valve 427 also supported by rotatable arm 424. The regulator includes exhaust vents 428.

In operation, the rotatable arm 424 is moved to open an air passage through the inhalation area 420 and delivery tube 421 to thereby allow the air stream to flow in direction of arrow 429. The twist top may be activated to provide a method dose of powder to the inhalation area 420. The valves 423, 427 and rotable arm 424 may be adapted to substantially occlude the usual air pathway and thereby maximise powder pick up in the air stream. An equaliser hose may be provided to balance pressures between the medical chamber and regulator body. The medication canister 416 may be replaceable and preferably is replaced after any episode use.

Figure 16 shows a delivery system for a dry powder held in blister packs. An inactive arrangement 510A includes a snorkel 511 and chamber 512 configured within the snorkel. Inspirational airflow in activated deployment is shown by arrow 513 towards mouthpiece 514 (only the base is shown). The therapeutic agent is stored in a blister roll 515 which is engaged with a cog roller 516 and then to a receiving spool 517. A gear drive 518 is arranged to drive the cog roller 516.

An inhalation area 519 with a rotatable impeller 520 is also positioned in the chamber 512. An inlet 521 is covered by a valve 522. An activation button 523 is positioned laterally of the ordinary airflow path. Exhaust vents and purge valves 524 are also provided.

The activated arrangement is shown in Figure 510B. The activation button 523 is depressed to compress spring 525 and concertina wall 526. This cases plate 527 to slide relative to the chamber 512. Inlet aperture 528 aligns with an inlet 521. Outlet aperture 529 aligns with air outlet 530 thereby creating new airflow pathway 531. The activation button 523 also causes the blister roll 515 to advance and rupture one or more blister packs and discharge the powder agent, preferably into co-operative position to rotatable impeller 520 for subsequent dispersal. Release of the activation button causes reversal of the components to a starting position.

A similar arrangement is shown in Figure 17 when configured in a regulator. Active 610A and inactive 610B positions are displayed. In this case however, a twist top 611 is used to activate cog roller 616. Drive to the chain of blister pack may come from one or more of the cog roller 616 and spool 617. The gear drive 618 may be an intermediary drive device. Exhaust vents 624 and diaphragm and purge/exhaust valves 631 are provided as is mouthpiece 632. An inhalation funnel 633 is rotatable between a closed position and active position as seen in 610B. When active, the funnel 633 provides an air pathway to the mouthpiece 632 for inhalation of agent. An equaliser hose 634 balances pressure between the chamber and regulator body.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in any country.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Those of skill in the art will therefore appreciate that, in light of the instant disclosure, various modifications and changes can be made in the particular embodiments exemplified without departing from the scope

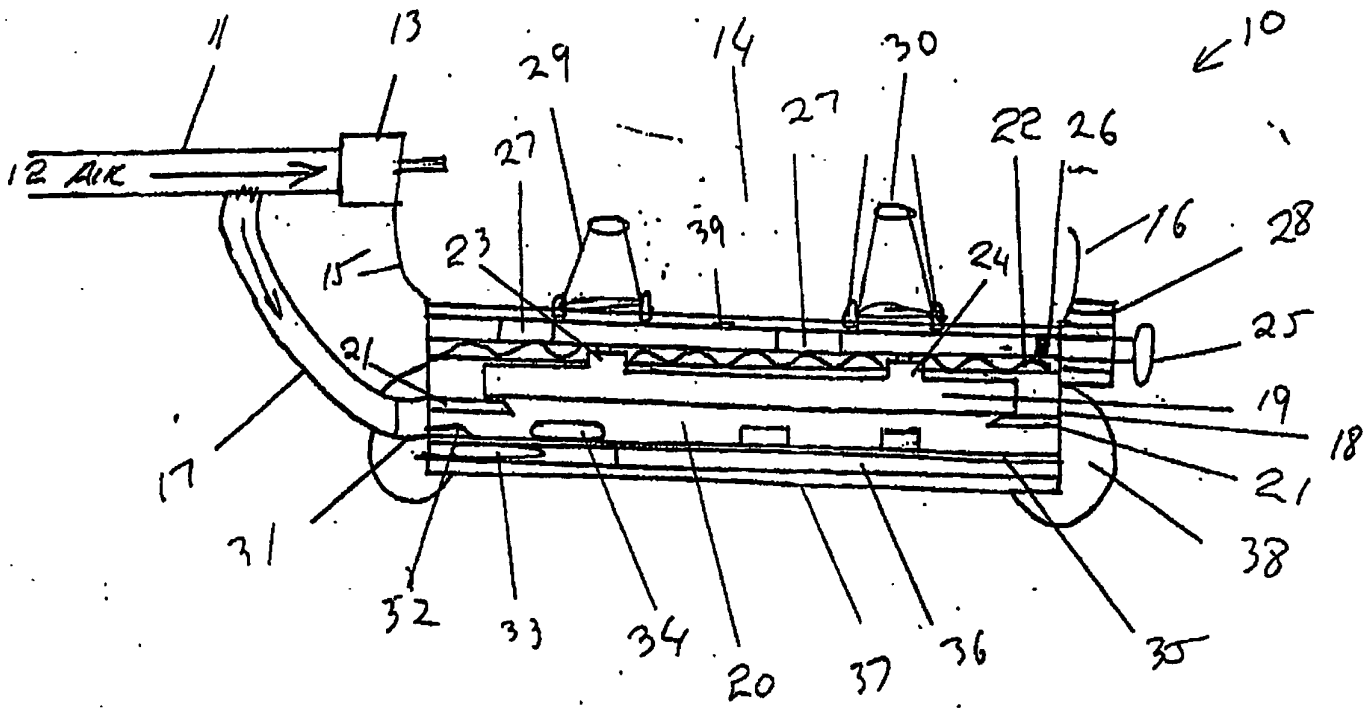
of the present invention. All such modifications and changes are intended to be included within the scope of the disclosure.

DATED this 11th day of July, 2003

David Peter Wharton

by DAVIES COLLISON CAVE

Patent Attorneys for the Applicants


11
13
29
14
30
10
12 AIR
27
27
22
26
16
28
23
39
24
15
25
21
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18
17
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31
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36
35

FIGURE 1

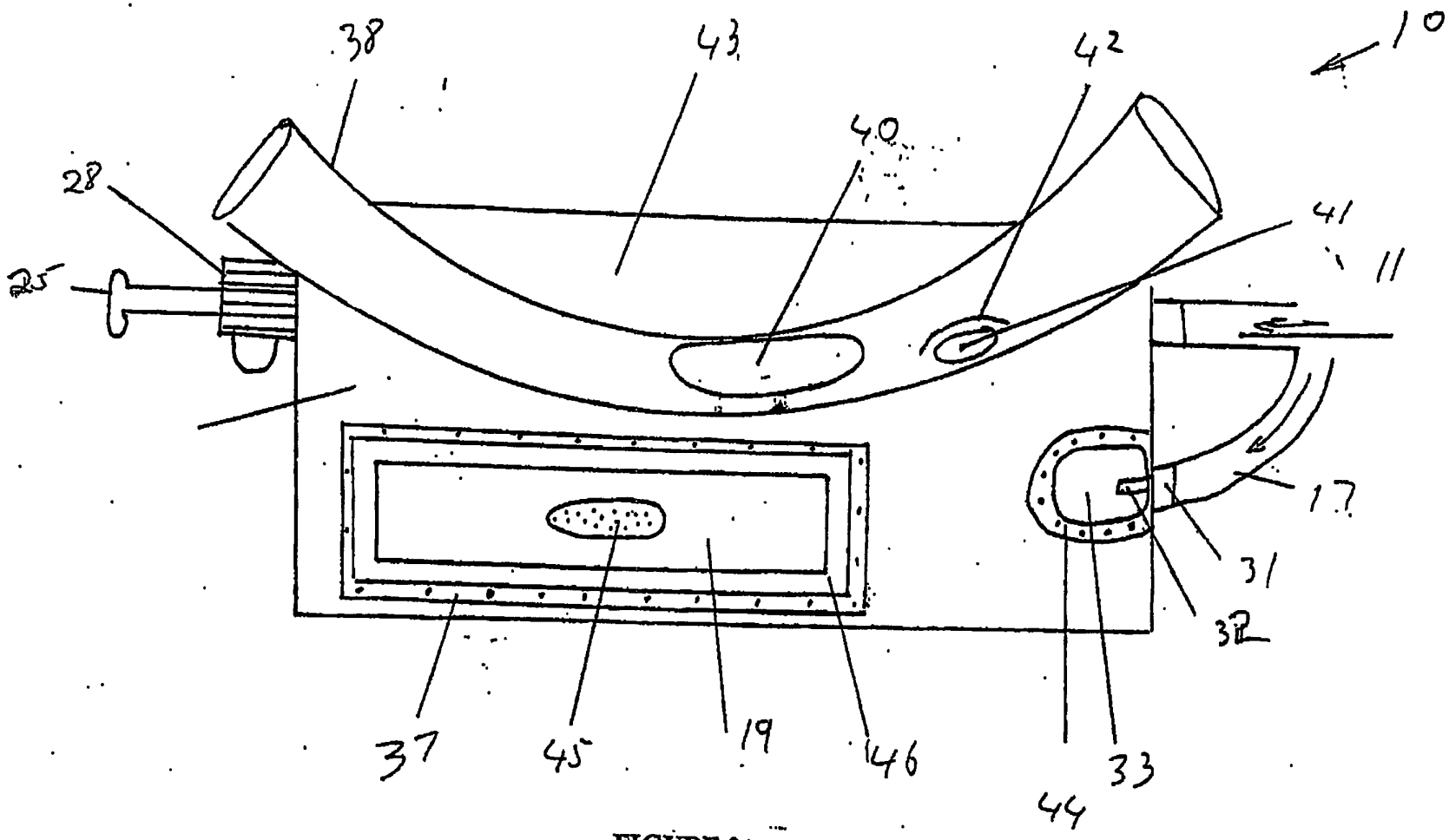


FIGURE 2

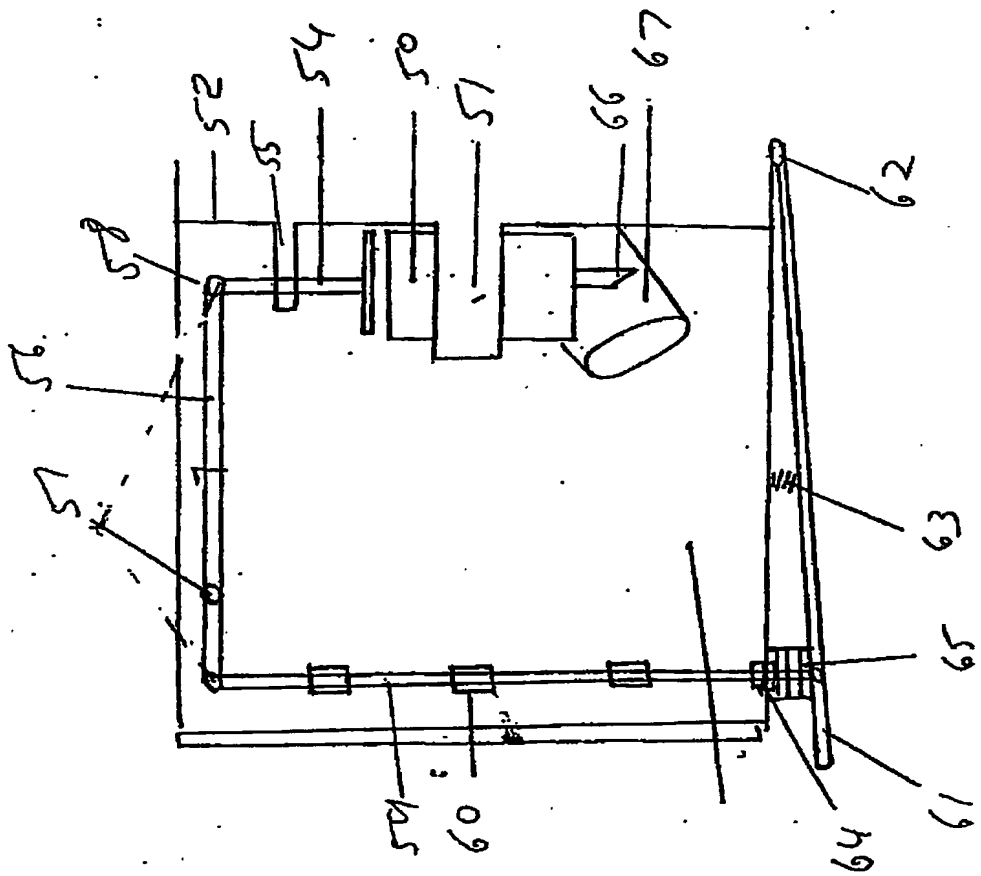


FIGURE 3

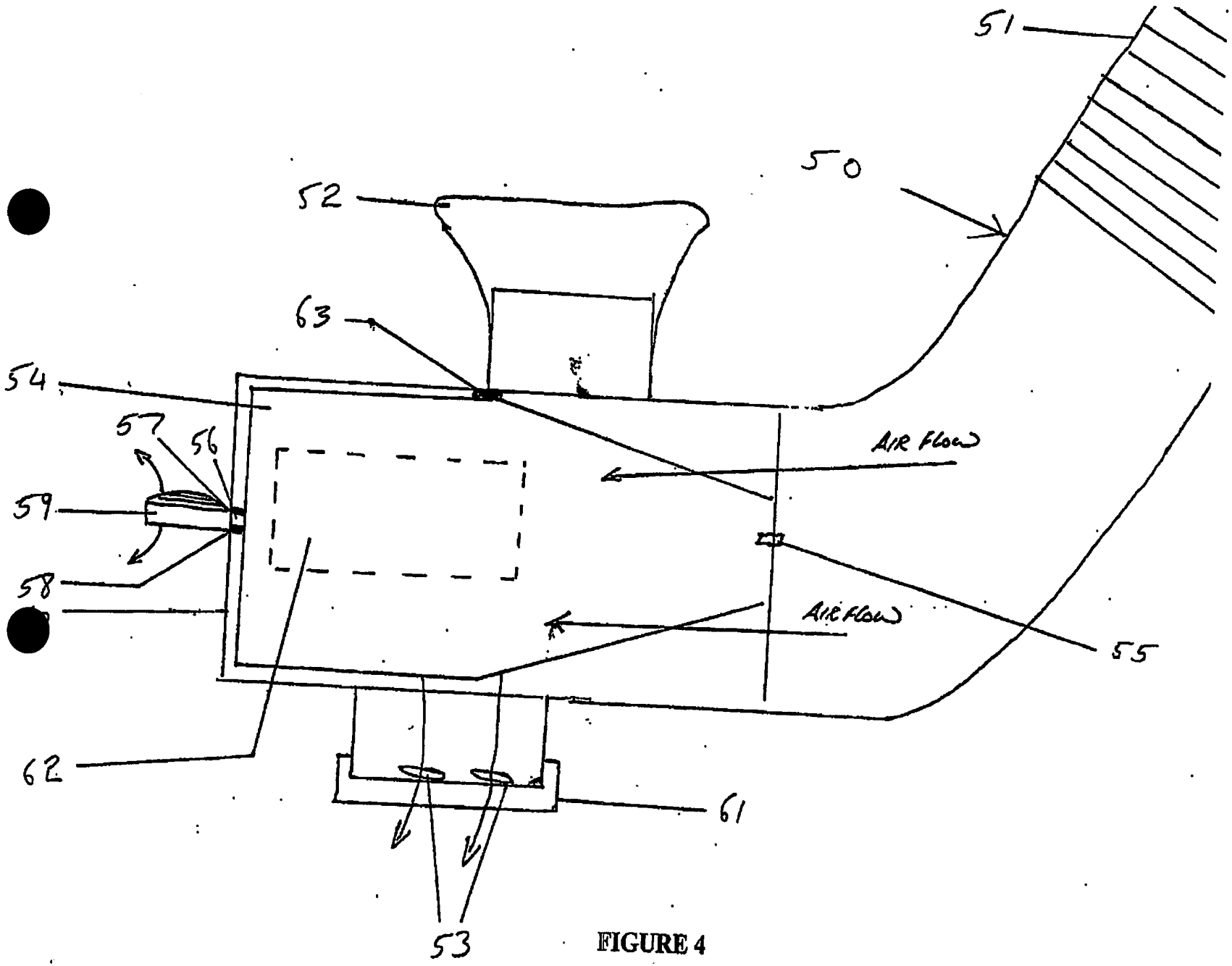


FIGURE 4

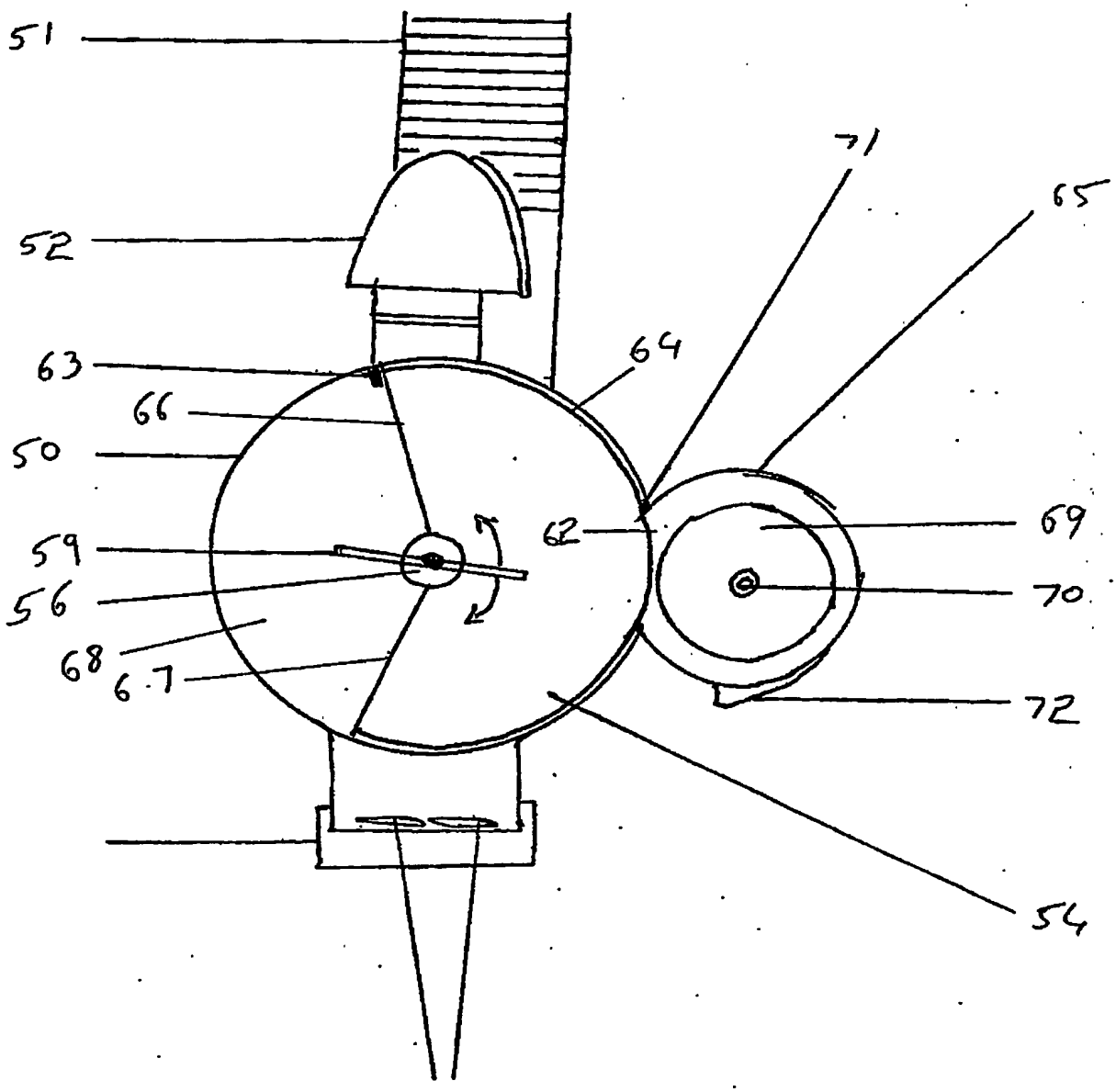
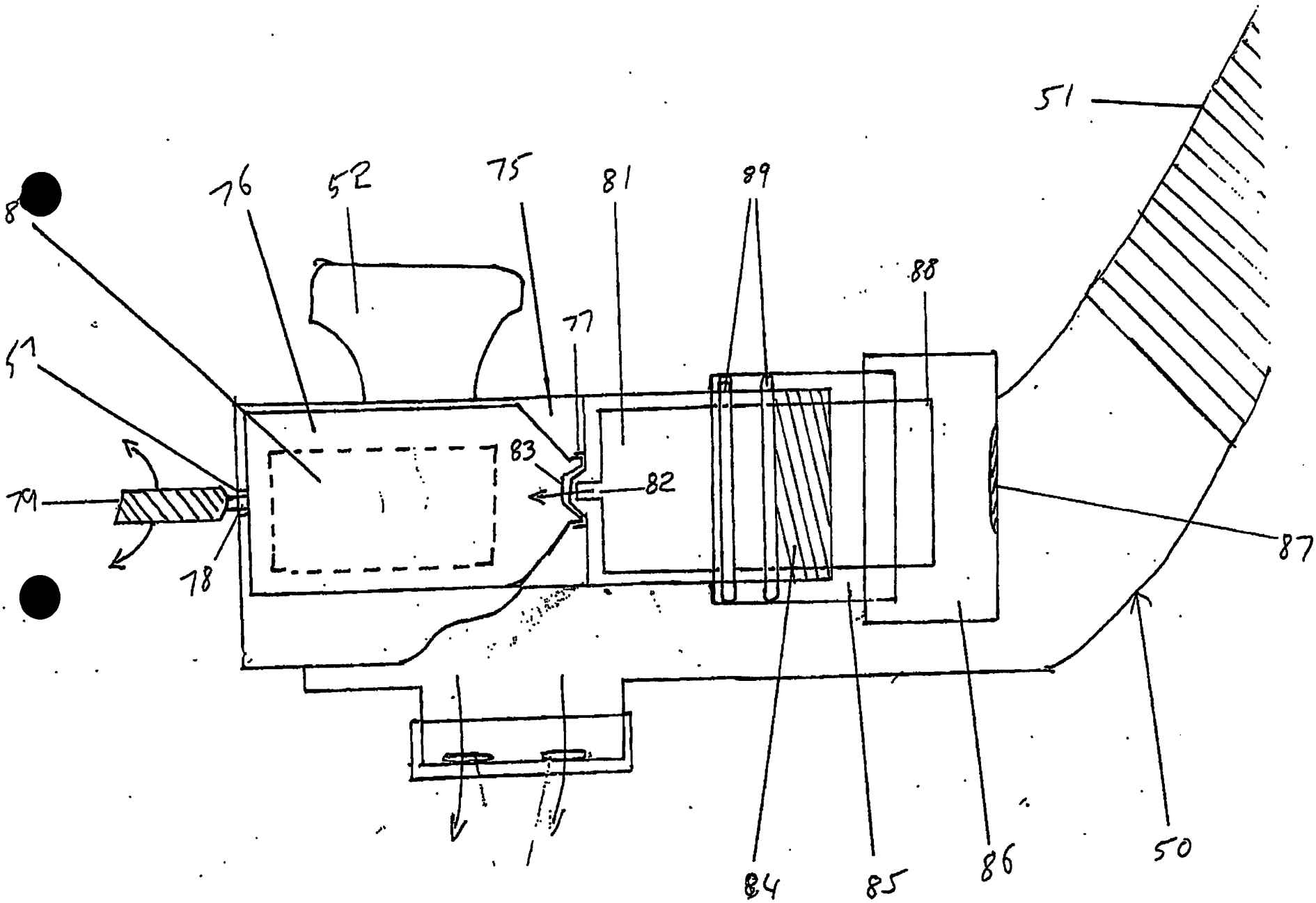


FIGURE 5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76
52
75
81
89
88
77
83
82
87
78
1
84
85
86
50

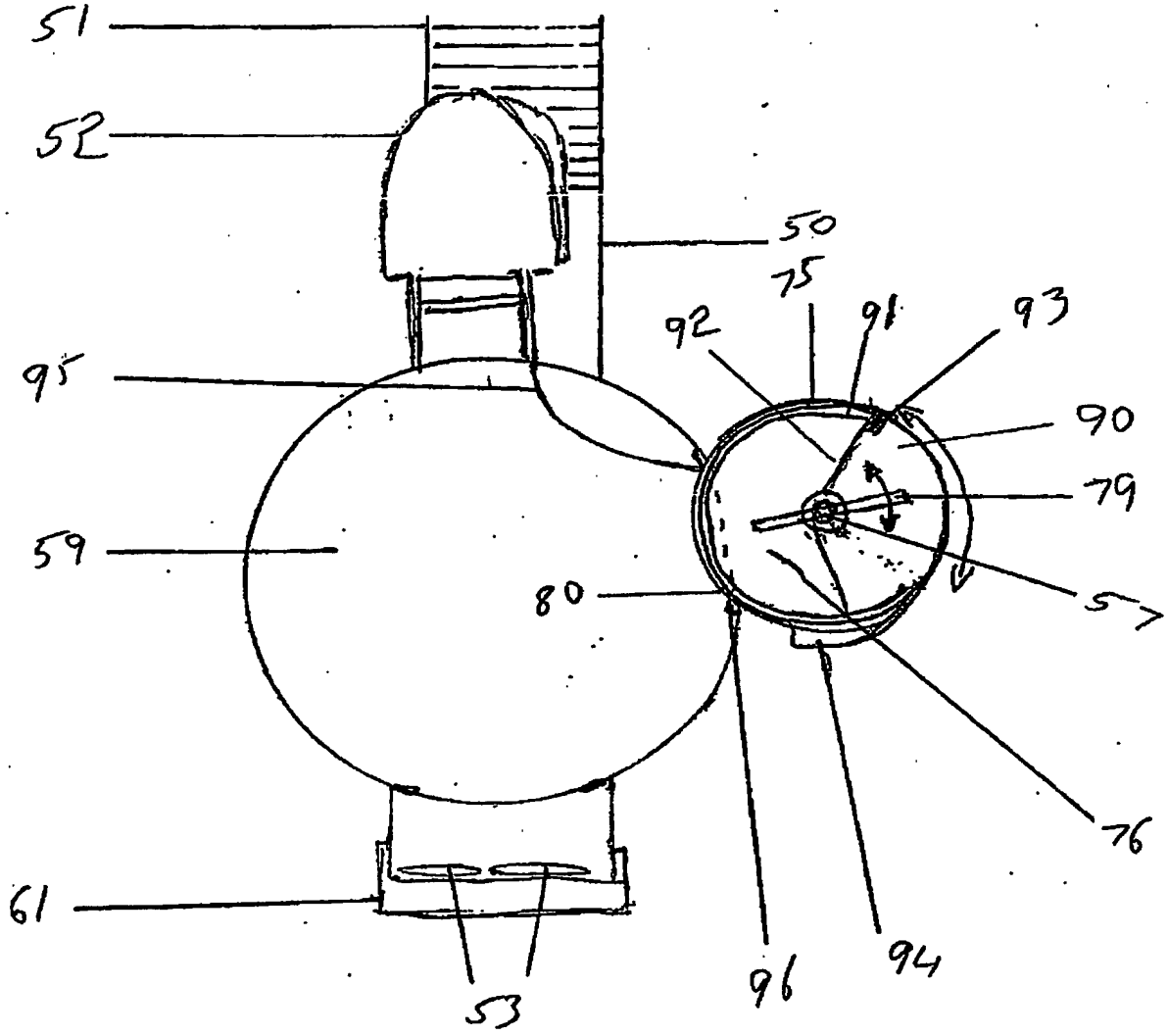


FIGURE 7

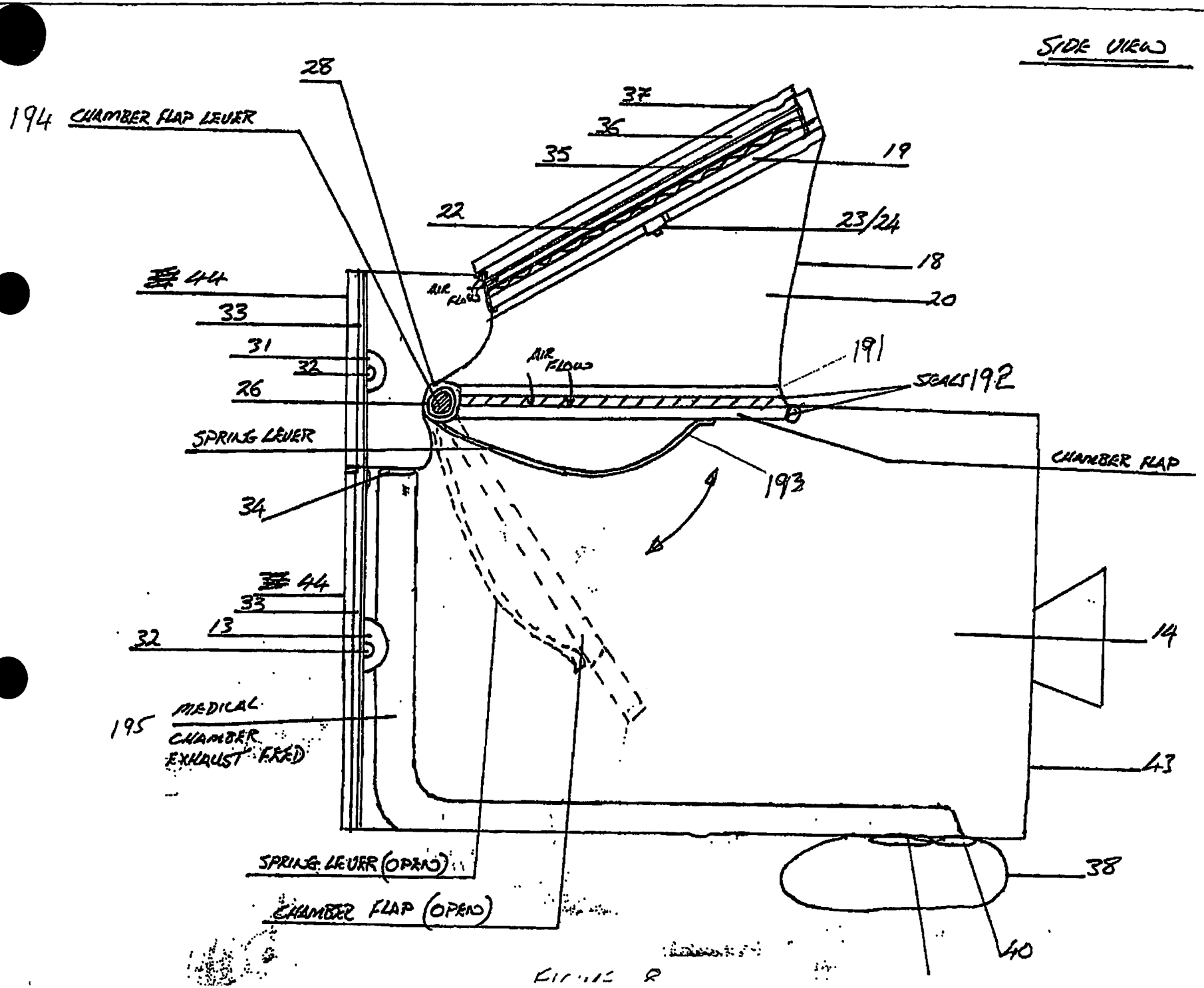
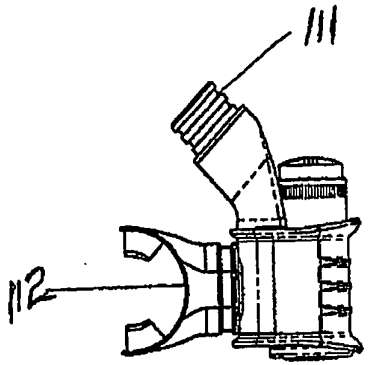
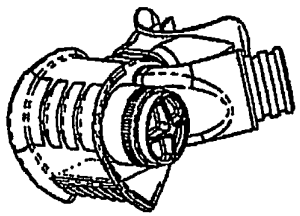

SIDE VIEW
28
194 CHAMBER FLAP LEVER
37
36
35
19
22
23/24
18
20
44
33
31
32
26
AIR FLOW
AIR FLOW
191
SEALS 192
SPRING LEVER
CHAMBER FLAP
193
34
44
33
13
32
14
195 MEDICAL CHAMBER EXHAUST FAN
43
SPRING LEVER (OPEN)
CHAMBER FLAP (OPEN)
38
40

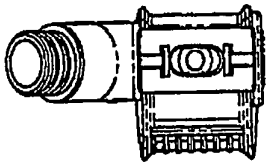
FIG. 2



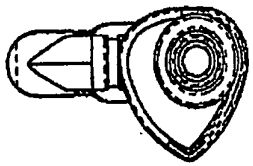
TOP VIEW



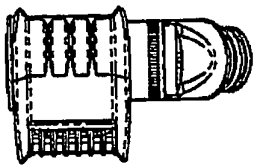
ANGLED VIEW



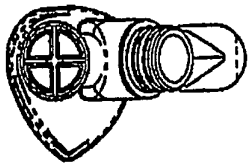
LEFT VIEW



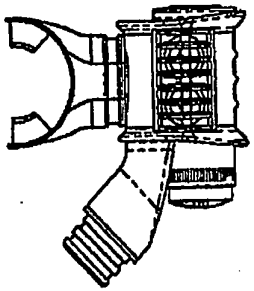
FRONT VIEW



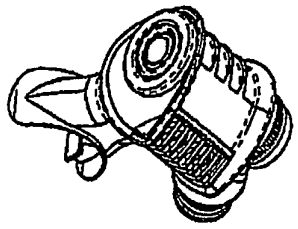
RIGHT VIEW



BACK VIEW



BOTTOM VIEW



ANGLED VIEW

FIGURE 9

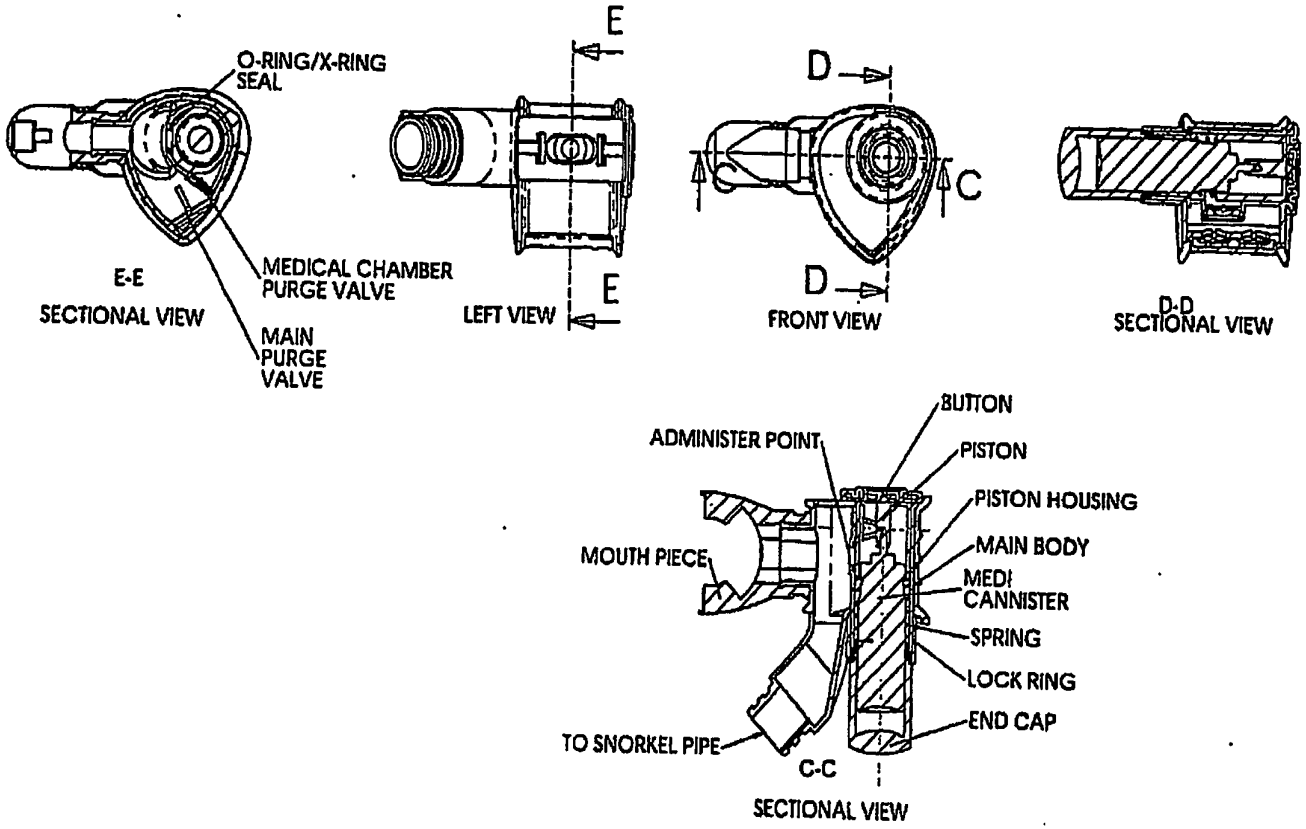

O-RING/X-RING SEAL
MEDICAL CHAMBER PURGE VALVE
MAIN PURGE VALVE
E-E
SECTIONAL VIEW
E
E
LEFT VIEW
D
D
FRONT VIEW
C
D-D
SECTIONAL VIEW
BUTTON
ADMINISTER POINT
PISTON
PISTON HOUSING
MAIN BODY
MOUTH PIECE
MEDI CANNISTER
SPRING
LOCK RING
END CAP
TO SNORKEL PIPE
C-C
SECTIONAL VIEW

FIGURE 10

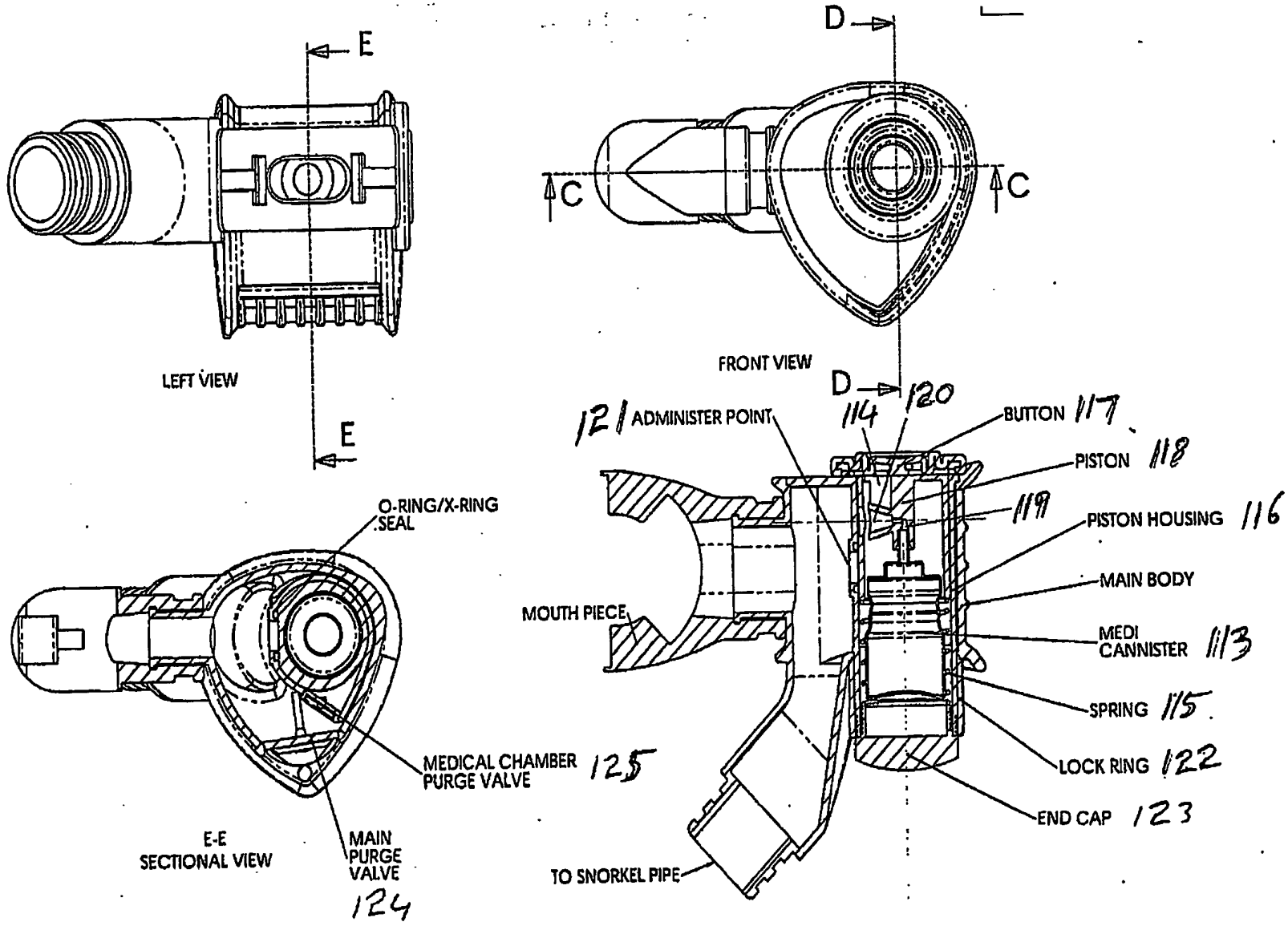
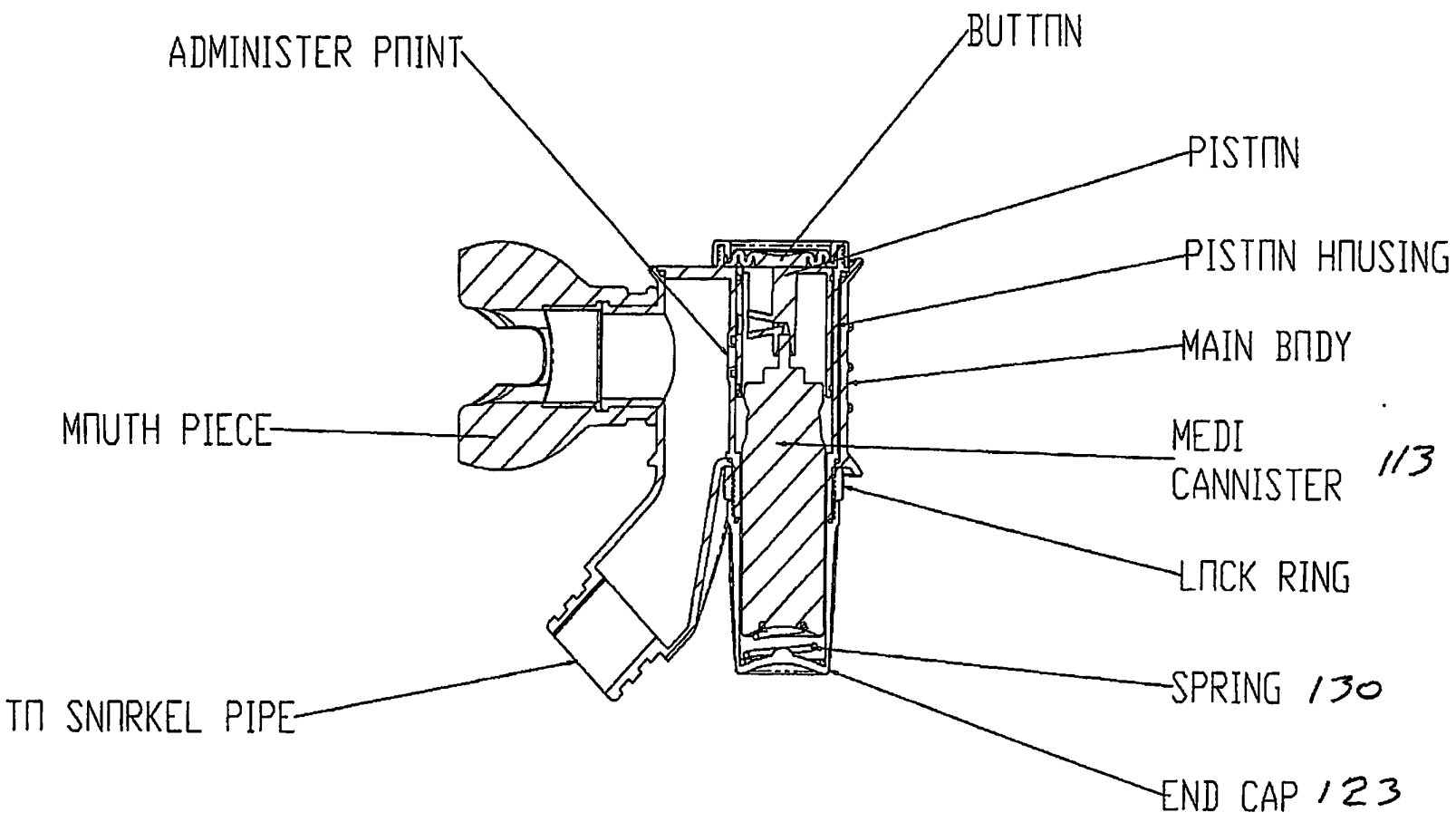

E
E
LEFT VIEW
D
C
C
FRONT VIEW
D
120
114
121 ADMINISTER POINT
BUTTON 117
PISTON 118
119
PISTON HOUSING 116
MAIN BODY
MOUTH PIECE
MEDI CANNISTER 113
SPRING 115
LOCK RING 122
END CAP 123
TO SNORKEL PIPE
O-RING/X-RING SEAL
MEDICAL CHAMBER PURGE VALVE 125
MAIN PURGE VALVE 124
E-E SECTIONAL VIEW

FIGURE 11

Medidive Pressurized Cannister Snorkel



SECTIONAL VIEW

FIGURE 12

Medidive Pressurized Cannister Regulator

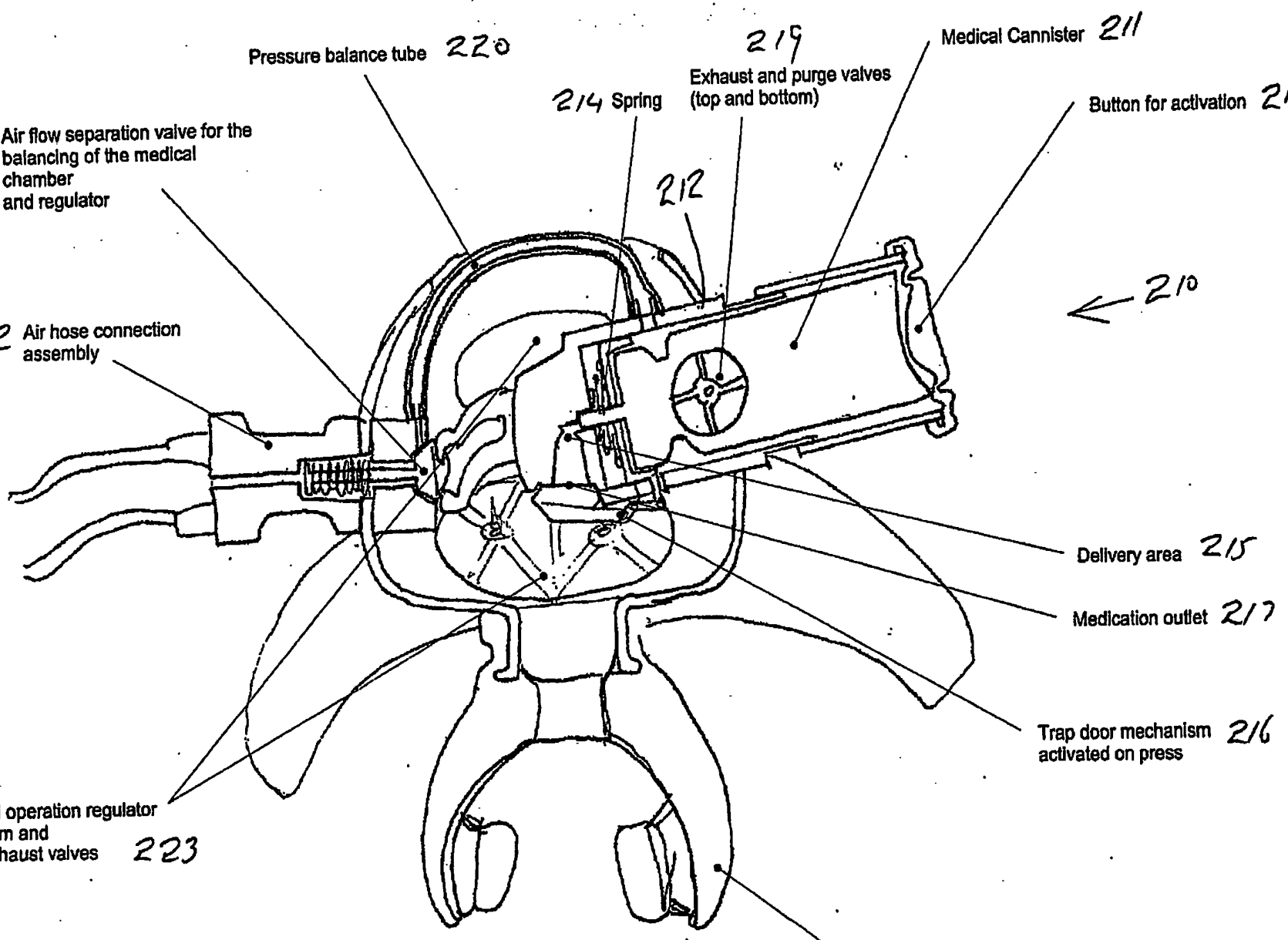
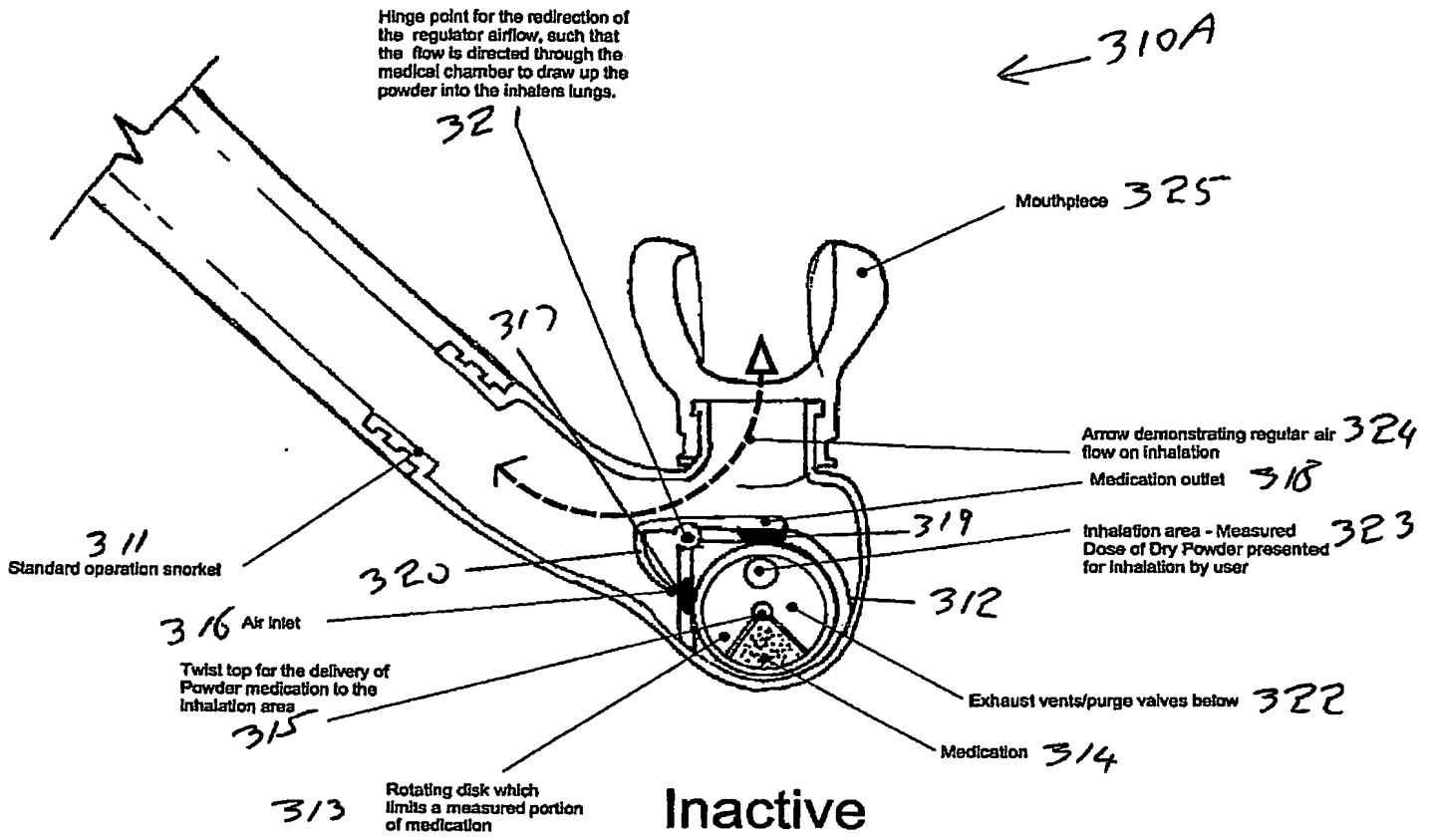
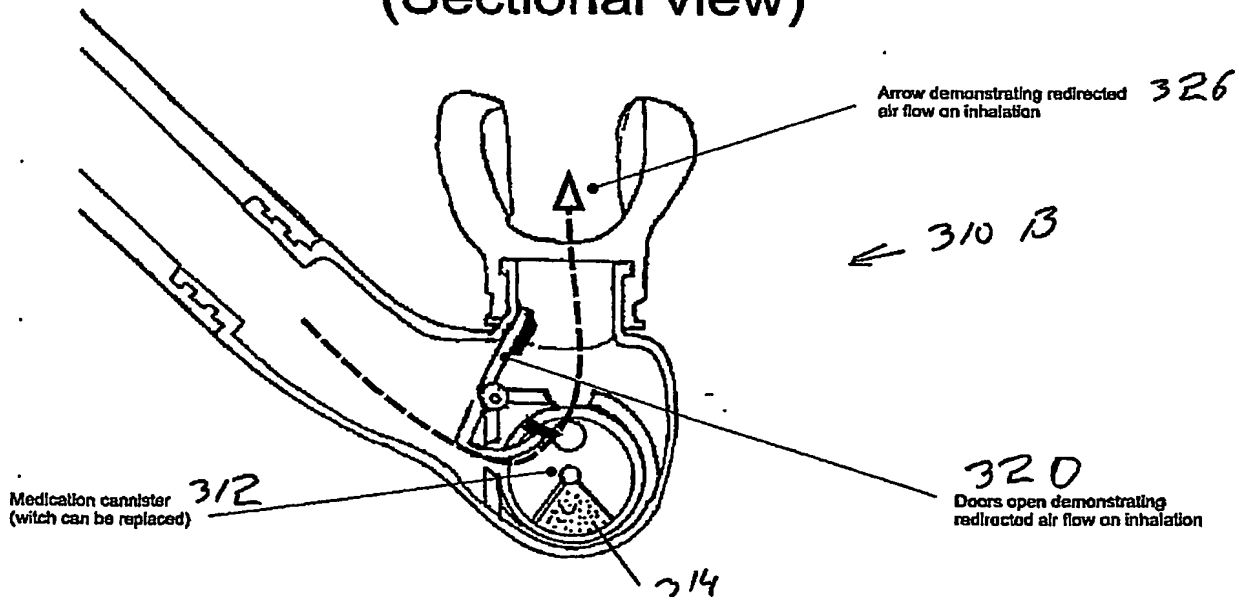


FIGURE 13 (Sectional view)

Medidiv Dry Powder Snorkel



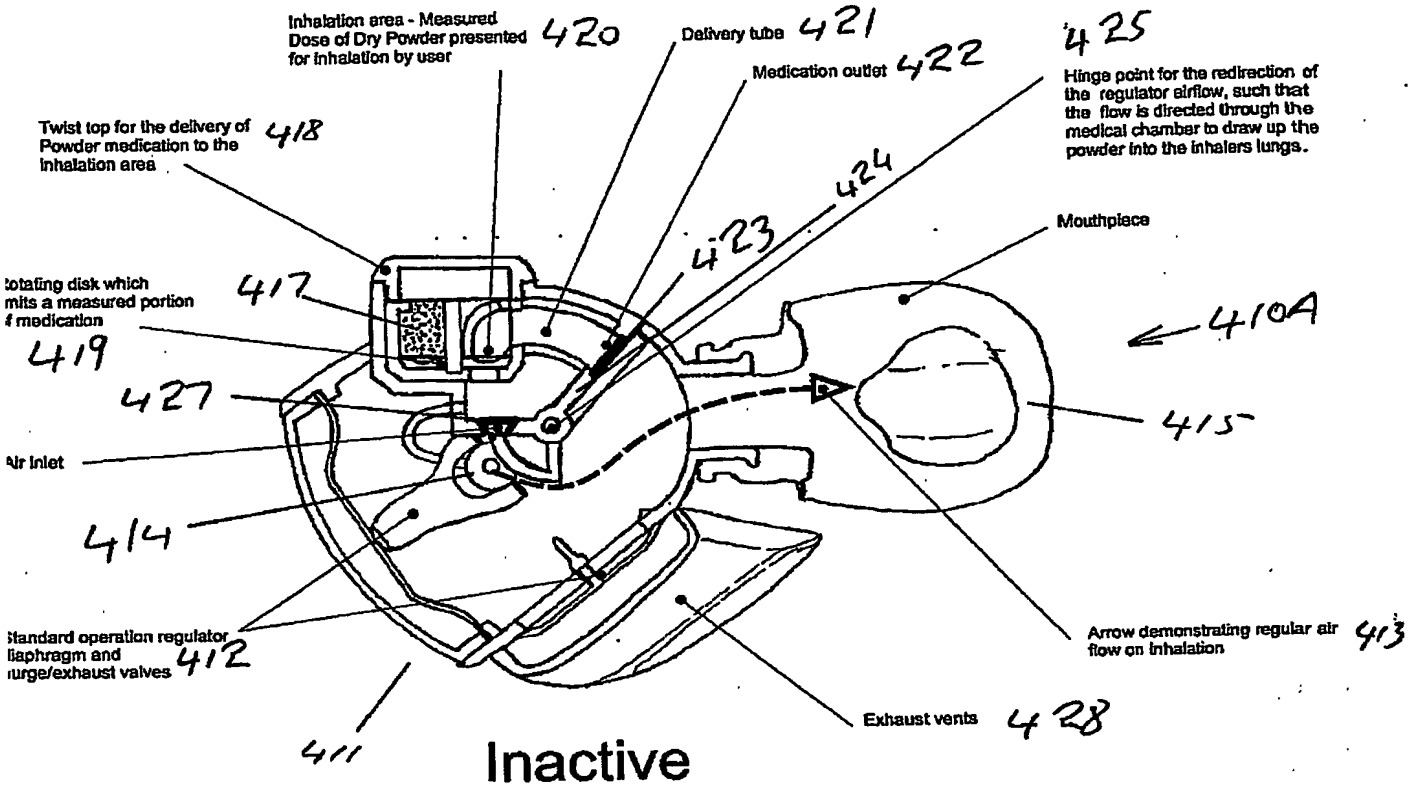
Inactive
(Sectional view)



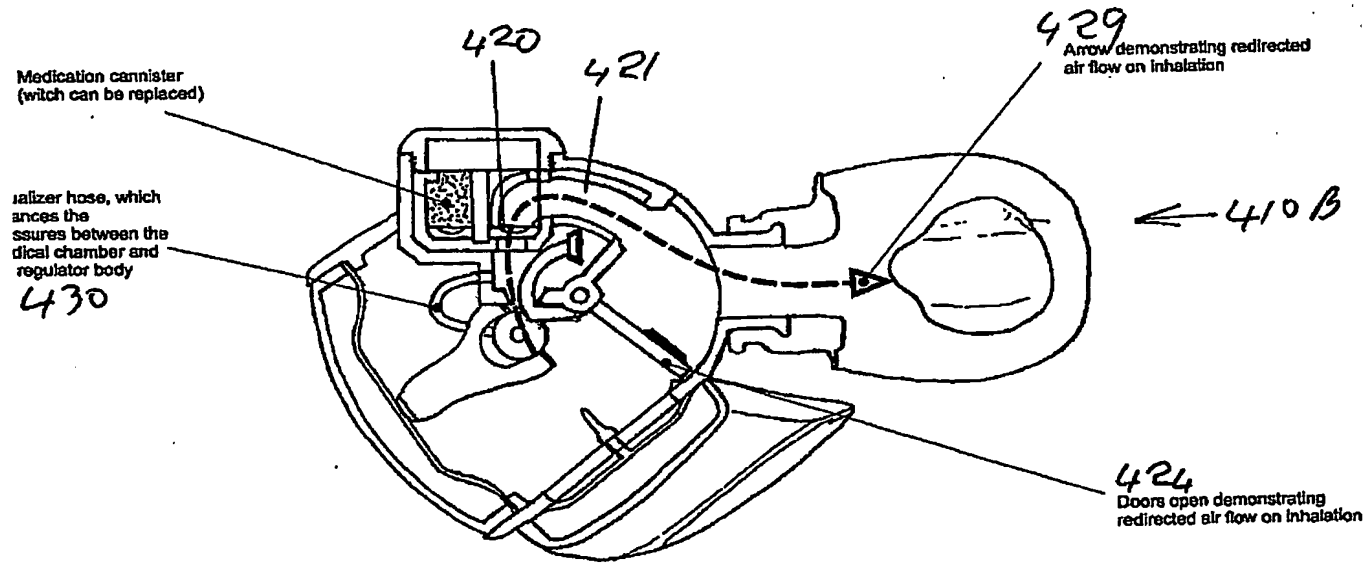
Activated
(Sectional view)

FIGURE 14

Medidive Dry Powder Regulato



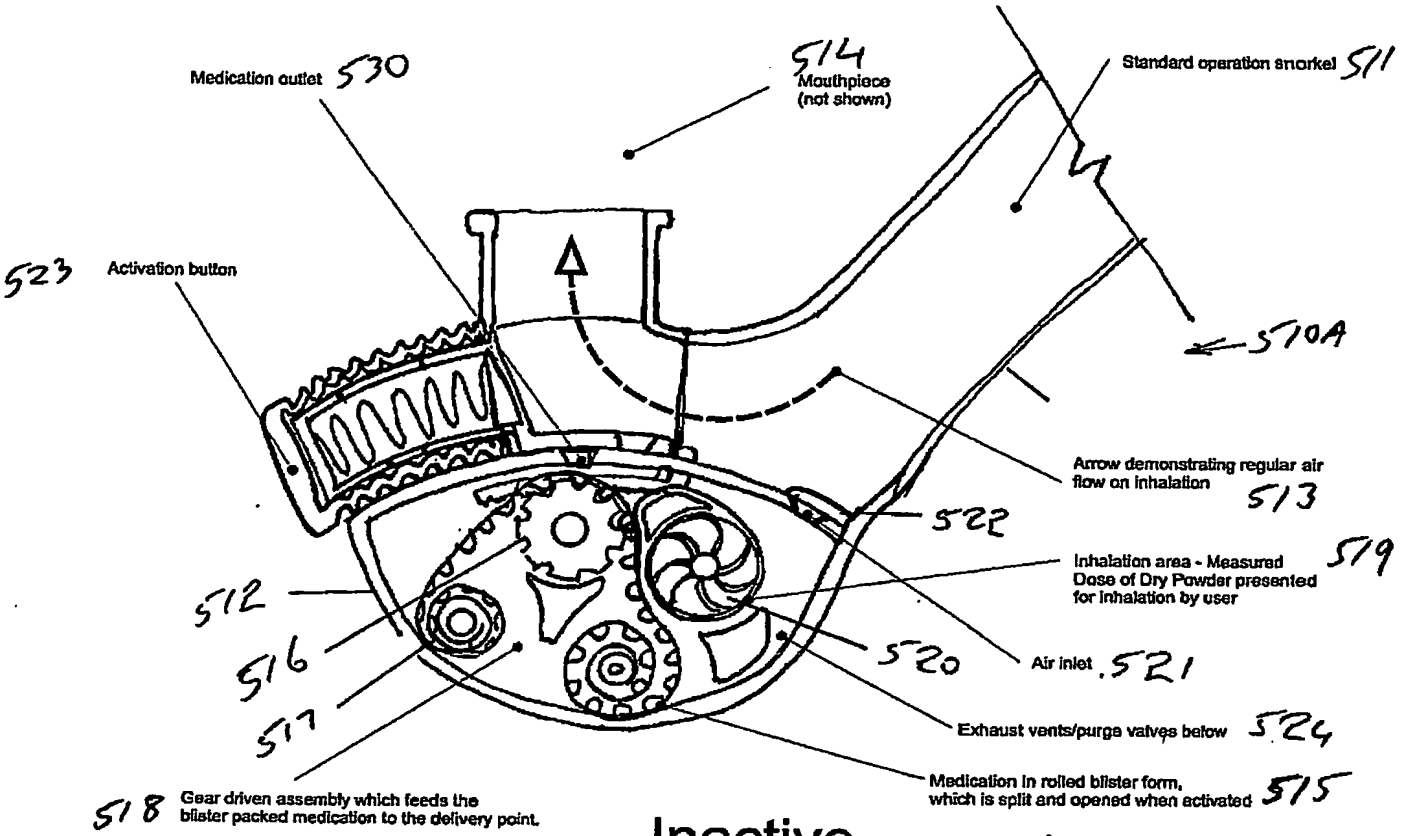
Inactive
(Sectional view)



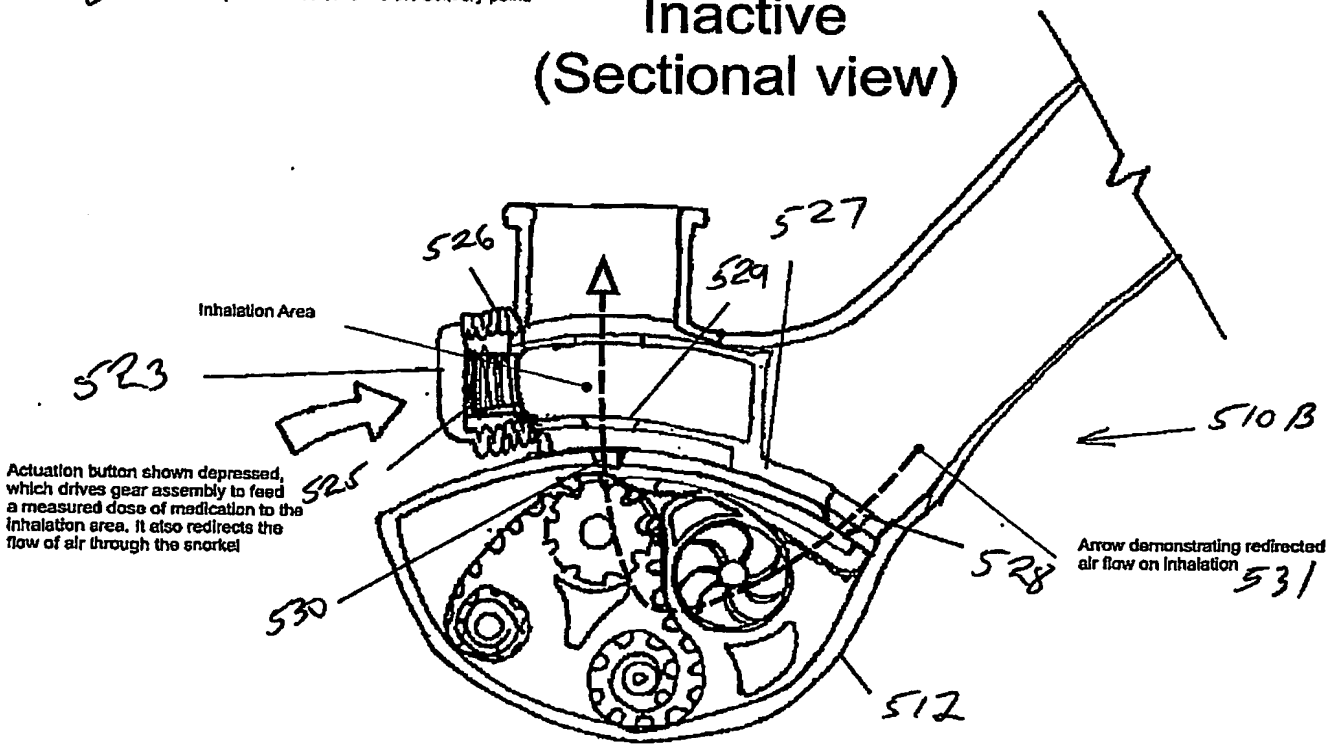
Activated
(Sectional view)

FIGURE 15

Medidive Dry Powder (Blister) Snorkel



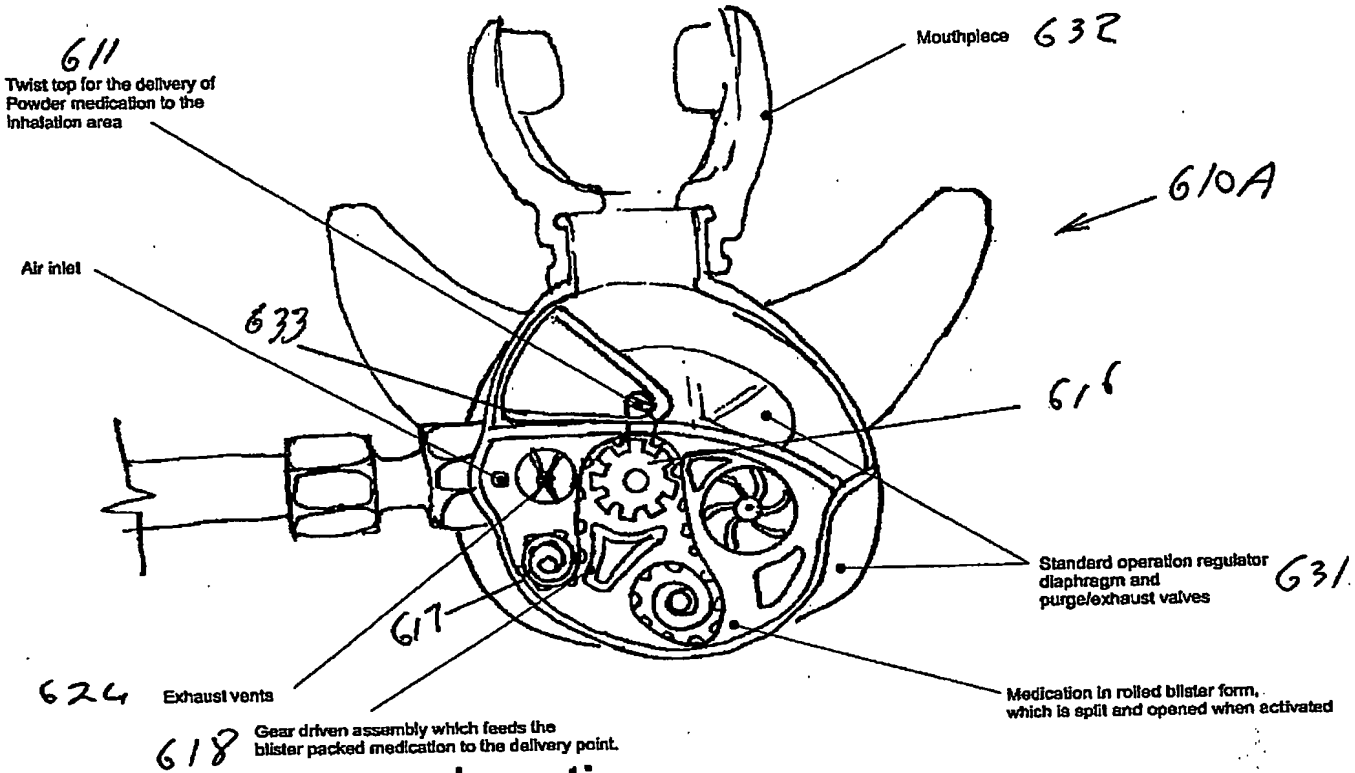
Inactive
(Sectional view)



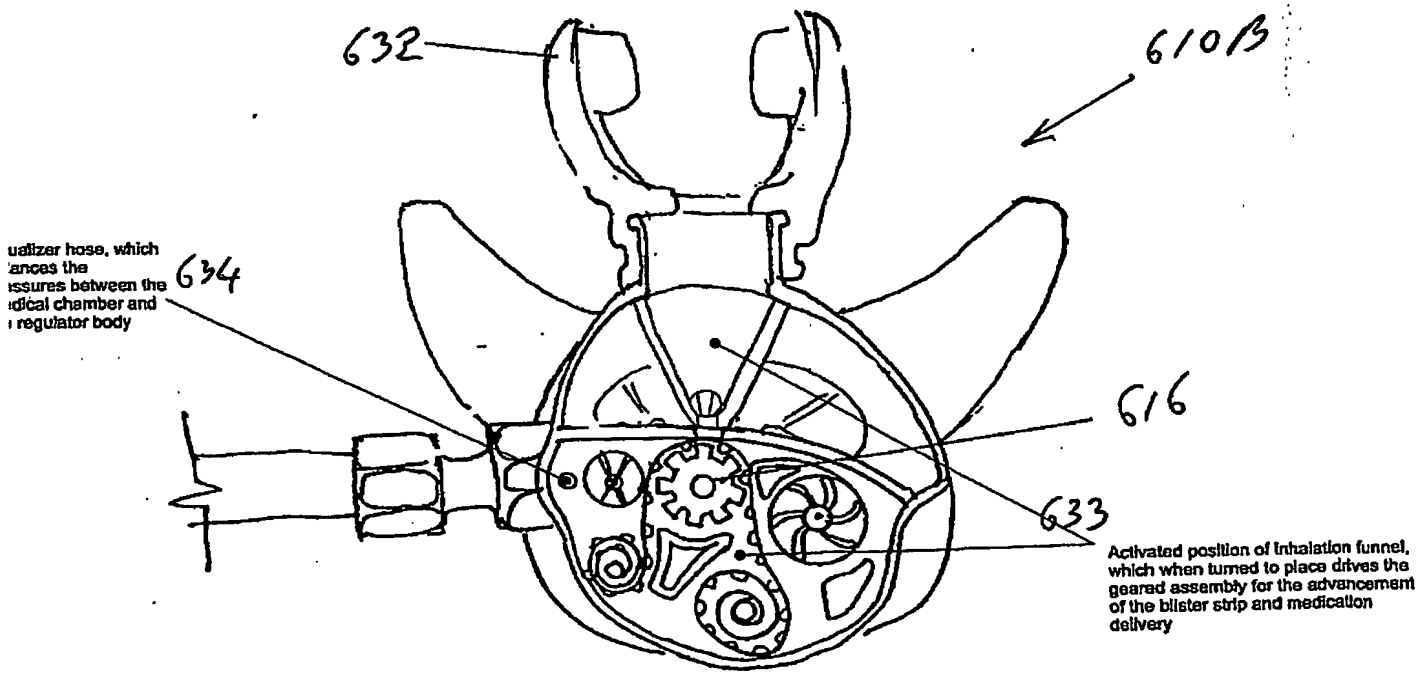
Activated
(Sectional view)

FIGURE 16

Medidive Dry Powder (Blister) Regulator



Inactive
(Sectional view)



Activated
(Sectional view)

FIGURE 17